

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

Remarks/Arguments

Claims 1, 40, 45 and 46 have been amended; new Claim 60 has been added; and Claim 18 has been cancelled without prejudice. Accordingly, Claims 1-17 and 19-60 are currently pending.

I. Amendments:

Amended Claim 1 is now directed to a method for including a hygroscopic ingredient in a moist composition for a controlled time period, which includes encapsulating the hygroscopic ingredient with a lipid coating in an amount sufficient to retain at least about 60 wt% of said hygroscopic ingredient after said encapsulated ingredient is combined with said moist composition for a time period of at least about 1 week and combining the encapsulated hygroscopic ingredient with the moist composition for a time period of at least about one week. Support for amended Claim 1 can be found throughout the specification and, more specifically, at page 13, lines 3-9 and in originally filed Claim 18. Accordingly, no new matter has been added to amended Claim 1.

Claim 40 has been amended to be consistent with amended Claim 1, Claim 45 has been amended to be consistent with Claim 21, and Claim 46 has been amended to depend from Claim 45 and to correct an error. As such, no new matter has been added.

New Claim 60 has been added, which depends from Claim 46. Support for Claim 60 can be found at page 14, lines 8-10. No new matter has been added.

II. The Invention:

The invention is directed to methods for including a hygroscopic ingredient in a moist composition and protecting the hygroscopic ingredient from the moist or humid environment for significant periods of time prior to its intended use (Claims 1-20) and, more specifically, to methods for the controlled protection of a hygroscopic bioactive substance contained in a moist ruminant feed composition (Claims 21-39).

The invention is also directed to a composition that includes a moist material in combination with a stabilized hygroscopic ingredient that is exposed to the moist material for a significant time period, in which the hygroscopic ingredient is stabilized with a controlled-protection lipid coating sufficient to retain a controlled amount of the ingredient for the period of exposure and prior to its intended use (Claims 40-60). In one embodiment, the invention is directed to a ruminant feed containing a hygroscopic bioactive substance that is protected for a significant storage period in the moist feed and thereafter through the rumen portion of the ruminant's digestive system (Claims 45, 46 and 60).

The prior art references do not disclose compositions that include a combination of a moist material and a hygroscopic ingredient protected with a controlled-protection lipid coating for the significant storage periods, as claimed.

III. Rejections:

Applicant thanks Examiner Sayala for extending the courtesy of a telephone communication with Applicant's representative on September 30, 2003, to discuss the status of Claims 21-39. Based upon a review of the Office Action and the discussions with Examiner Sayala, Applicant respectfully submits that Claims 21-39 were mistakenly listed as rejected on the Office Action Summary page of the Office Action and were not rejected in the Detailed Action. Accordingly, it is respectfully requested that the Office Action Summary be corrected to indicate that Claims 21-39 are allowed.

Rejections based on Fielding et al.

On pages 2-3 of the Office Action, Examiner Sayala rejected Claims 1-5, 7-9, 15-20, 40-43, 47-48 and 52-56 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,206,049 to Fielding et al. (hereinafter "Fielding et al.").

Fielding et al. is directed to compositions containing mixtures of sodium chloride and choline-containing compounds which are effective as salt substitutes. Fielding et al. teach that the shelf life of the compositions, when in granular or crystalline form, can be increased by partially coating the granules with a hydrophobic material. (See Col.3, line 65 to Col.4, line 1). Fielding et al. further teach that it is important to not completely coat the aggregate with a water-insoluble layer as this would prevent water from contacting the aggregate and thus prevent the dissolution and release of the sodium chloride and choline chloride when used on foods or when eaten. (See Col.7, lines 22-27).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir. 1989).

Regarding Claim 1, nowhere do Fielding et al. disclose a method which includes encapsulating (i.e., completely surrounding) a hygroscopic ingredient to provide the protection as claimed or combining the encapsulated ingredient with a moist composition for the claimed time period. As to Claim 40, again Fielding et al. do not disclose a composition that includes a moist material and a stabilized hygroscopic ingredient that is encapsulated with a controlled-protection lipid coating which will offer the claimed protection after being exposed to the moist material for the claimed time period.

In fact, Fielding et al. actually teach away from encapsulating the choline-containing composition by teaching that the composition should only be partially coated with a hydrophobic material. This partial coating would not provide the claimed protection for a hygroscopic ingredient that is exposed to a moist material.

Therefore, as Fielding et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is

respectfully submitted that Fielding et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

As to the Examiner Sayala's contention that Claims 3-5, 15-20, 41-43 and 52-56 recite limitations that are either inherent in or would have been obvious over Fielding et al., it is respectfully submitted that the claimed invention is not inherently present in or obvious over the teachings of Fielding et al.

In order to rely on the theory of inherency, "The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464(Bd. Pat. App. & Inter. 1990) (emphasis in original).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. See MPEP § 2142.

The teaching or suggestion to make the claimed combination (or modification) and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, the reference must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Thus, unless there is some suggestion or motivation contained within the reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with the moist composition (e.g., moist ruminant feed) having all the claim limitations, a *prima facie* case of obviousness cannot be established.

It is respectfully submitted that the claimed level of protection for the hygroscopic ingredient is not inherently possessed by the coated materials disclosed by Fielding et al., i.e., the disclosed coatings do not necessarily provide the claimed protection. Moreover, there is no suggestion or motivation in the Fielding et al. reference to modify its teachings to provide the claimed methods and compositions. More specifically, there is no suggestion or motivation to encapsulate the hygroscopic ingredient to provide the claimed protection or to provide a composition with the claimed storage time.

As discussed above, Fielding et al. teach away from encapsulating the choline-containing substance and, instead, clearly teach that it should only be partially coated.

Accordingly, it is respectfully requested that the rejections of claims 1-5, 7-9, 15-20, 40-43, 47-48 and 52-56 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Fielding et al., be withdrawn.

Rejections based on Klose

On page 4 of the Office Action, Examiner Sayala rejected Claims 1-20 and 40-59 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,109,755 to Klose (hereinafter "Klose").

Klose is directed to a method for administering a bioactive substance to the post rumen portion of the digestive system of a ruminant. The method involves orally administering a composition containing the bioactive substance encapsulated with a hydrophobic coating in a quantity sufficient to essentially preclude introduction of the bioactive substance into the rumen.

Nowhere does Klose disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant.

Therefore, as Klose does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Klose cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Klose, since the encapsulates of Klose do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Klose reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with the moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Klose teaches away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teaches away from an encapsulate having the claimed protection from the moist material. In this regard, Klose teaches that the encapsulate is directly orally administered to the ruminant (See Col.3, lines 18-30). Further, there is no teaching or suggestion by Klose to combine the encapsulates with moist feed for a period of about one week prior to feeding to the ruminant. Thus, one of ordinary skill in the art would understand that the encapsulates of Klose are effective for direct administration to the ruminant, but not for extended exposure to a moist feed, as claimed. Therefore, it is respectfully submitted that the encapsulates disclosed by Klose would not provide the claimed protection and actually teach away from the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-20 and 40-59 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Klose, be withdrawn.

Rejections based on King et al.

On pages 4-5 of the Office Action, Examiner Sayala rejected Claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,807,594 to King et al. (hereinafter "King et al.").

King et al. is directed to a feedstuff additive containing choline for enhancing weight gain and feed efficiency in a ruminant and a method of enhancing weight gain and feed efficiency in a ruminant. The method involves administering to the ruminant a feed efficiency enhancing amount of choline, wherein the method of administration minimizes decomposition of the choline in the rumen.

Nowhere do King et al. disclose combining an encapsulate with a moist feed for a period of time of at least about 1 week, prior to feeding to the ruminant, or an encapsulate which provides the claimed protection from the moist feed.

Therefore, as Klose does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Klose cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by King et al., since the encapsulates of King et al. do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the King et al. reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with the moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, King et al. teach away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teach away from an encapsulate having the claimed protection from the moist material. In this regard, King et al. teach that the choline capsules can be fed directly to the ruminant or

can be mixed with the moist feed immediately prior to feeding. (See Col.5, lines 37-58)
More specifically, King et al. teach that the choline capsules can be mixed with a base mix or premix ration which has a similar particle size or can be applied on top of the feed before being consumed (i.e. top dressed). King et al. also teach that the encapsulating composition must protect the choline from metabolism by microorganisms in the rumen, but also have the ability to dissipate in the post rumen portion of the digestive system. (See Col.4, lines 9-14). Thus, in order for the encapsulate to be capable of being directly fed to the ruminant and to dissipate in the post rumen portion of the digestive system, it is respectfully submitted that it would necessarily have a coating that is insufficient to provide protection from exposure to moist feed for a period of at least 1 week prior to feeding to the ruminant.

Therefore, it is respectfully submitted that there is no teaching, suggestion or motivation to one skilled in the art, based on the King et al reference, to arrive at the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of King et al., be withdrawn.

Rejections based on Blagdon et al.

On pages 5-6 of the Office Action, Examiner Sayala rejected Claims 1-11 and 40-56 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,496,571 to Blagdon et al. (hereinafter "Blagdon et al.").

Blagdon et al. is directed to a method of increasing the production of milk in a ruminant by orally administering a milk-production increasing effective amount of encapsulated choline to the ruminant. The core of the encapsulate is a water solution of choline and the shell protects the core from the rumen portion of the digestive system.

Blagdon et al. do not disclose encapsulating a hygroscopic ingredient, as claimed. The encapsulated solution of choline in water, e.g. a 70% solution of choline, is not a hygroscopic ingredient as claimed. In order to be considered a hygroscopic ingredient, it must readily absorb moisture or water from the surrounding environment or be degraded by the presence of water or moisture in the outside environment (See application at page 7, lines 24-29).

Therefore, as Blagdon et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Blagdon et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Blagdon et al., since the encapsulates of Blagdon et al. do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Blagdon et al. reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with the moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Blagdon et al. teach away from encapsulating a hygroscopic ingredient and instead teach that the encapsulate should include a core of a water solution of choline.

Accordingly, it is respectfully requested that the rejections of claims 1-11 and 40-56 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Blagdon et al., be withdrawn.

Rejections based on Kitamura et al.

On pages 6-7 of the Office Action, Examiner Sayala rejected Claims 1-11 and 40-56 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,676,966 to Kitamura et al. (hereinafter "Kitamura et al.").

Kitamura et al. is directed to a granular additive composition for ruminant feed which stably protects a biologically active substance in the rumen and allows it to be digested and absorbed in the digestive organs after the abomasum.

Nowhere do Kitamura et al. disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant, or providing a composition which contains an encapsulate having the claimed protection, i.e., an encapsulate having the claimed protection from exposure to a moist material for a period of at least about 1 week.

Therefore, as Kitamura et al. do not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Kitamura et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Kitamura et al., since the encapsulates of Kitamura et al. do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Kitamura et al. reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with the moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Kitamura et al. teach away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teach away from an encapsulate having the claimed protection from the moist material. In this regard, Kitamura et al. teach that the coating amount of the coating composition should be as low as possible, but in an amount to sufficiently protect the biologically active substance from the rumen (See Col.5, lines 30-35). Thus, it is respectfully submitted that one of ordinary skill in the art would understand that the encapsulates of Kitamura et al. are only effective for direct administration to the ruminant, i.e., directly feeding or top dressing the feed. Therefore, it is respectfully submitted that the encapsulates

disclosed by Kitamura et al. would not provide the claimed protection and actually teach away from the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-11 and 40-56 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Kitamura et al., be withdrawn.

Rejections based on Iijima et al.

On pages 7-8 of the Office Action, Examiner Sayala rejected Claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,948,589 to Iijima et al. (hereinafter "Iijima et al.").

Iijima et al. is directed to a granular composition for a ruminant containing choline. The granular composition is prepared by granulating the choline with a binder under low humidity and thereafter overcoating the granule with a hydrophobic over-coating.

Nowhere do Iijima et al. disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant, or providing a composition which contains an encapsulate having the claimed protection, i.e., an encapsulate having the claimed protection from exposure to a moist material for a period of at least about 1 week.

Therefore, as Iijima et al. do not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Iijima et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Iijima et al., since the encapsulates of Iijima et al. do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Iijima et al. reference to modify its

teachings to include the encapsulated hygroscopic ingredient in combination with the moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Iijima et al. teach away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teach away from an encapsulate having the claimed protection from the moist material. In this regard, Iijima et al. teach that the overcoated granules are suitable for directly feeding to the ruminant, i.e., the granules are capable of passing through the rumen without being easily dissolved or decomposed (See Col.2, lines 3-9). Iijima et al. further teach that the overcoat layer provides the protection from the rumen. (See Col.5, lines 47-53 and Comparative Example 1). Iijima et al. further teach that the encapsulate is protected with an overcoat layer that includes a solubility modifier to provide protection from the rumen portion of the digestive tract in a ratio to the hydrophobic agent in the range of 1:0.2-1, preferably 1:0.25-1 (See Col.6, line 67 to Col.7, line 6). The solubility modifier is described as being stable under neutral conditions (i.e., pH = 6-8) and soluble under acid conditions (See Col.3, line 62 to Col. 4, line 3). As moist ruminant feed is acidic in pH (e.g., pH = approx. 4), the encapsulates disclosed by Iijima et al. would not be stable for at least about one week in such a moist feed. Therefore, it is respectfully submitted that the encapsulates disclosed by Iijima et al. would not provide the claimed protection and actually teach away from the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Iijima et al., be withdrawn.

Rejections based on Nishimura '198

On page 8 of the Office Action, Examiner Sayala rejected Claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,635,198 to Nishimura et al. (hereinafter "Nishimura '198").

Nishimura '198 discloses a feed or feed additive granular agent containing a physiologically active substance and a coating layer having a laminar structure. The coating layer contains a fatty acid or ester thereof, a fat or fatty oil, a wax and tubular crystals of a substance which is sparingly water-soluble under neutral conditions but is readily water-soluble under acidic conditions.

Nowhere does Nishimura '198 disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant, or a composition which contains an encapsulate having the claimed protection, i.e., an encapsulate having the claimed protection from exposure to a moist material for a period of at least about 1 week.

Therefore, as Nishimura '198 does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Nishimura '198 cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Nishimura '198, since the encapsulates of Nishimura '198 do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Nishimura '198 reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with a moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Nishimura '198 teaches away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teach away from an encapsulate having the claimed protection from the moist material. In this regard, Nishimura '198 teaches encapsulates that rely on a coating containing a pH sensitive material, that is stable under neutral conditions and soluble under acidic conditions, to protect the encapsulate from the rumen portion of the digestive tract (See Col.7, line 58 to Col.8, line 2, and Table 2). As discussed above with regard to Iijima et al., these encapsulates would not remain stable in a moist ruminant feed for a period of at least

Applicant: Paul H. Richardson
Application Serial No.: 10/043,085
Filing Date: January 9, 2002
Docket No.: 1001-12
Reply to Non-Final Office Action mailed 1001-12
Page 24 of 29

about one week. As such, one skilled in the art would understand this to mean that these encapsulates are effective for direct administration to the ruminant, but not for extended exposure to a moist feed, as claimed. Therefore, it is respectfully submitted that the encapsulates disclosed by Nishimura '198 would not provide the claimed protection and actually teach away from the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Nishimura '198, be withdrawn.

Rejections based on Nishimura '527

On page 9 of the Office Action, Examiner Sayala rejected Claims 1-13, 15-20 and 40-56 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,571,527 to Nishimura et al. (hereinafter "Nishimura '527").

As Nishimura '527 is the parent application to Nishimura '198 and the disclosures are essentially the same, it is respectfully submitted that the present claims are not anticipated by and are not obvious over Nishimura '527 for the same reasons discussed above with respect to Nishimura '198.

Accordingly, it is respectfully requested that the rejections of claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Nishimura '527, be withdrawn.

Rejections based on Ando et al.

On pages 9-10 of the Office Action, Examiner Sayala rejected Claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,713,245 to Ando et al. (hereinafter "Ando et al.").

Ando et al. is directed to a granule containing a physiologically-active substance, which is stable under neutral conditions and disintegrates or dissolves under acidic conditions.

Nowhere do Ando et al. disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant, or a composition which contains an encapsulate having the claimed protection, i.e., an encapsulate having the claimed protection from exposure to a moist material for a period of at least about 1 week.

Therefore, as Ando et al. do not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Ando et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Ando et al., since the encapsulates of Ando et al. do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Ando et al. reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with a moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Ando et al. teach away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teach away from an encapsulate having the claimed protection from the moist material. In this regard, Ando et al. teach that the encapsulates rely on a pH sensitive material, that is stable under neutral conditions and soluble under acidic conditions, to protect the encapsulate from the rumen portion of the digestive tract (See Col.3, lines 1-21, and the Examples). As discussed above with regard to Iijima et al., these encapsulates would not remain stable in a moist ruminant feed for a period of at least about one week. As such, one skilled in the art would understand this to mean that these encapsulates are effective for direct administration to the ruminant, but not for extended exposure to a moist feed, as claimed. Therefore, it is

respectfully submitted that the encapsulates disclosed by Ando et al. would not provide the claimed protection and actually teach away from the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Ando et al., be withdrawn.

Rejections based on Ueda `166

On pages 10-11 of the Office Action, Examiner Sayala rejected Claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,227,166 to Ueda et al. (hereinafter "Ueda `166").

Ueda `166 is directed to a feed additive for ruminants. The feed additive includes a biologically active substance that is stable in the rumen of ruminants and released in the abomasum and its subsequent digestive tract.

Nowhere does Ueda `166 disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant, or a composition which contains an encapsulate having the claimed protection, i.e., an encapsulate having the claimed protection from exposure to a moist material for a period of at least about 1 week.

Therefore, as Ueda `166 does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Ueda `166 cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Ando et al., since the encapsulates of Ueda `166 does not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Ueda `166 reference to modify its

teachings to include the encapsulated hygroscopic ingredient in combination with a moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Ueda `166 teaches away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teaches away from an encapsulate having the claimed protection from the moist material. In this regard, Ueda `166 teaches that the encapsulates are protected by a coating that includes an inorganic substance that is stable under neutral conditions and soluble under acidic conditions (See Col. 4, lines 30-36, and Tables 1 and 2). As discussed above with regard to the references that rely on pH sensitive materials for protection from the rumen, these encapsulates would not remain stable in a moist ruminant feed for a period of at least about one week. As such, one skilled in the art would understand this to mean that these encapsulates are effective for direct administration to the ruminant, but not for extended exposure to a moist feed, as claimed. Therefore, it is respectfully submitted that the encapsulates disclosed by Ueda `166 would not provide the claimed protection and actually teach away from the claimed invention.

Accordingly, it is respectfully requested that the rejections of claims 1-13, 15-20 and 40-58 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Ueda `166 be withdrawn.

Rejections based on Ueda `832

On pages 11-12 of the Office Action, Examiner Sayala rejected Claims 1-20 and 40-59 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,429,832 to Ueda et al. (hereinafter "Ueda `832").

Ueda `832 is directed to a feed additive composition for ruminants. The feed additive composition includes a biologically active substance that is coated with a coating composition which is stable in the rumen and which releases the active substance in the abomasum and the subsequent digestive tract.

Nowhere does Ueda '832 disclose combining an encapsulate with a moist feed for any significant period of time, let alone for at least about 1 week, prior to feeding to the ruminant, or a composition which contains an encapsulate having the claimed protection, i.e., an encapsulate having the claimed protection from exposure to a moist material for a period of at least about 1 week.

Therefore, as Ueda '832 does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Ueda '832 cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Moreover, the claimed invention is not inherently disclosed by Ueda '832, since the encapsulates of Ueda '832 do not necessarily provide the claimed protection. Further, there is no suggestion or motivation contained within the Ueda '832 reference to modify its teachings to include the encapsulated hygroscopic ingredient in combination with a moist composition (e.g., moist ruminant feed) having all the claim limitations.

In fact, Ueda '832 teaches away from combining the encapsulated bioactive material with the moist feed for a significant period of time, e.g. at least about one week, as claimed, and teaches away from an encapsulate having the claimed protection from the moist material. In this regard, similar to Ueda '166, Ueda '832 again relies on a significant amount of a material that is pH sensitive to protect the encapsulate from release in the rumen portion of the digestive tract (See Col.3, lines 19-25). As discussed above with regard to the references that rely on pH sensitive materials for protection from the rumen, these encapsulates would not remain stable in a moist ruminant feed for a period of at least about one week. As such, one skilled in the art would understand this to mean that these encapsulates are effective for direct administration to the ruminant, but not for extended exposure to a moist feed, as claimed. Therefore, it is respectfully submitted that the encapsulates disclosed by Ueda '166 would not provide the claimed protection and actually teach away from the claimed invention.

Applicant: Paul H. Richardson
Application Serial No.: 10/043,085
Filing Date: January 9, 2002
Docket No.: 1001-12
Reply to Non-Final Office Action mailed 1001-12
Page 29 of 29

Accordingly, it is respectfully requested that the rejections of claims 1-20 and 40-59 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a), in view of Ueda '832, be withdrawn.

CONCLUSION

Applicants respectfully submit that the application as amended, including claims 1-17 and 19-60, is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to examination of the application, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



Robert C. Morriss
Registration No.: 42,910
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550
RCM:jp